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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,974

02/27/2007

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

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1628

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,974	Applicant(s) ZOFCHAK ET AL.	
	Examiner Sabiha Qazi	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/25/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) 25-28, 31, 32, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24, 29, 30, 33-36 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 25-28, 31, 32, 37, 38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Non-Final Office Action

Claims 21-39 are pending. No claim is allowed. Amendments are entered.

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 112 (2) Rejection
5. 35 USC § 112 (1) Rejection
6. 35 USC § 103(a) Rejection
7. Response to Remarks
8. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicant may become aware in the specification.

35 USC § 112 --- First Paragraph Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reason apply:

The term “among many others” is not defined in the specification. It may include many known or unknowns. The specification does not provide a clear definition of the terms as are claimed. It appears that Applicant has no possession of the terms at the time the invention was filed. Applicant is requested to explain this issue.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.’)

Mere indistinct terms (such as “among many others” used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement.

A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize

the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying

characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

The courts have stated that reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. See *Genentech v. Novo Nordisk A/S* (CAFC) 42 USPQ2d 1001 (1997).

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132.

The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him. See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at

the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

It appears that in present case Applicant has no possession of the claimed prodrug in this application. Applicant is requested to explain

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 21-24, 29, 30, 33-36 and 39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:
3. There is lack of antecedent basis in claims 29 and 30 for “personal care product” in claim 21.
4. Recitation of “among numerous others” at the end of the claim 39.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-24, 29, 30, 33-36 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over EMMONS et al.¹; Jones, Charles E² (from 10/714,772). These references teach urethane derivatives useful for personal care products which embrace presently claimed invention.

EMMONS teaches low molecular weight thickeners, characterized by hydrolytic stability, versatility and efficiency, and to a wide variety of aqueous systems containing the thickeners. The thickeners provide a combination of properties not found in any one class of known thickeners. For example, they are nonionic and in many cases are highly efficient viscosity improvers although having a relatively low molecular weight. They are stable to water and alcohol and are not sensitive to biodegradation. They are versatile in that not only do they thicken virtually unlimited types of aqueous systems, but they also impart many of

¹ US Patent 4,079,028

the auxiliary properties described above. Thus, as additives to textile binder compositions, they actually soften rather than harden the fabric. The reference further teaches that urethane polymers having at least three low molecular weight hydrophobic groups at least two of which are terminal (external) hydrophobic groups. Many of the polymers also contain one or more internal hydrophobic groups. The hydrophobic groups together contain a total of at least 20 carbon atoms and are linked through hydrophilic (water soluble) groups containing polyether segments of at least about 1,500, preferably at least about 3,000, molecular weight each so that the polymers readily solubilize in water, either by self-solubilization or through interaction with a known solubilizing agent such as a water miscible alcohol or surfactant. The molecular weight of the polyurethanes is of the order of about 10,000 to 200,000.

The hydrophobic groups of the polyurethanes occur in the residues of reactants (b) and (c) and may also occur in the residue of reactant (d) if present. The terminal (external) hydrophobes are the residues of the monofunctional active hydrogen compounds, organic monoisocyanates, or combinations of the residues of such compounds. The polymers may be substituted for known thickeners in any

² EP 0875 237 B1

aqueous system in which thickeners are normally utilized and therefore the fields of use of the thickeners of the invention include a host of industrial, household, medical, personal care and agricultural compositions. The thickening in such compositions is often also accompanied by other improvements, such as leveling, flow, stabilization, and suspension; high and low shear viscosity control, and binding properties. See the entire document especially abstract, and summary of the invention, Example 280 (drawn to cosmetics) and example 281 drawn to useful protein hair conditioner.

JONES teaches a method of thickening a hair dye composition comprising at least one polyethoxylated urethane. See the entire document especially [0016], [0019][0021, [0023].

The composition has improved thickening and shear thinning properties. The resistance of hair dye composition to drip or run once applied to the hair is enabled by viscosity at low shear rate. The ease of hair dye composition application to air is effected by viscosity at high shear rate after application by thickening due to interaction of hydrophobic modified nonionic polymer with itself. The hair dye include a rheology modifying system containing at

least one hydrophobically modified nonionic polymer (HNP) and at least one associative agent.

The hydrophobically modified nonionic polymer (HNP) preferably thickens by association, meaning that the HNP interacts or associates with it and other components in hair dye compositions to provide thickening. The hair dye composition, as applied to the hair, preferably contains at least 0.1 weight percent, preferably from 0.1 weight percent to 15 weight percent, and more preferably from 0.2 weight percent to 5 weight percent HNP, based on the total weight of the hair dye composition applied to the hair and based on the HNP being 100 weight percent solid polymer.

The HNP contains at least one hydrophobic group. The hydrophobic group is any chemical group that promotes water insolubility and includes, for example, alkyl, or aralkyl groups containing from about 4 to about 30 carbon atoms. Hydrophobic groups also include, for example, the hydrocarbon residues of hydroxyl, amino **or isocyanate** reactants, or any portion or segment of the polymeric reaction product that contributes to water insolubility. In addition, the HNP is nonionic which means it has no charge when dissolved or dispersed in aqueous solutions. Preferably, the HNP is

water soluble or water swellable. **Suitable HNPs include for example polyethoxylated urethane**, or hydrophobically modified naturally derived polyols such as a hydrophobically modified cellulose, or hydrophobically modified starch, or combinations thereof. The most preferred HNP is a polyethoxylated urethane.

The hydrophobically modified cellulose is a cellulose containing derivative which has been modified with at least one hydrophobic group. The hydrophobic groups are typically introduced by well known methods to functionalize some portion of the free hydroxyl groups in the cellulose polymer. Preferably, the hydrophobic group is a C.sub.4 to C.sub.20 alkyl or aralkyl group. Preferred hydrophobically modified cellulose is a cetyl hydroxyethylcellulose.

Instant claims differ from the reference in claiming a method of use of specific urethanes for personal care products wherein prior art teaches other uses including the use in personal care products.

It would have been obvious to one skilled in the art to prepare additional beneficial compositions to prepare personal care products with increased viscosity because prior art teaches the same. One skilled in the art would be

motivated to use urethane derivatives in order to adjust or increase the solubility of any personal care products. Applicants in the disclosure have no showing of any criticality or any new use. In view of the teachings of the prior art present invention is considered obvious.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

Applicant's response filed on 10/25/10 is hereby acknowledged. Applicants have elected group I with traverse, claims 21-24, 29, 30, 33-36 and 39. The method of use claims will rejoined (same scope) when compounds will be considered allowable. Applicant argues that there should not be any restriction. According to them there is not burden to search all the claims.

Examiner disagrees because claims are clearly drawn to compounds, their products and method of use. The search will not be the same for the methods for example only claim 39 is rejected under 112 (1) not all the examined claims are

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rejected. The reference used to reject the invention of group I may not be used for the group II.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fetterolf Brandon can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/

Primary Examiner, Art Unit 1628